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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/499,423	07/07/1995	CAREY V. CAMPBELL	MP/84	2478
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EXAMINER PELLEGRINO, BRIAN E				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

08/499,423

Applicant(s)

CAMPBELL ET AL.

Examiner

Brian E. Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,9,10,14-26 and 28-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,9,10,14-26 and 28-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date: _____

DETAILED ACTION

Claim Objections

Claim 30 is objected to because of the following informalities: the claim depends from a canceled claim. Appropriate correction is required.

Double Patenting

Applicant is advised that should claim 24 be found allowable, claim 28 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,3-7,9,10,14-16,19,20,23-26,28,29,30 are rejected under 35 U.S.C. 102(e) as being anticipated by Myers et al. (5628782). The applied reference has common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the

inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131. Fig. 5 shows a tube **11** covered with one or more layers of film **17**. Myers et al. disclose the tube is porous PTFE for a graft, col. 3, lines 14,59,60. Myers et al. additionally disclose the film covering the tube is porous PTFE, col. 4, lines 47-53. The use of "substantially unchanged" is terminology of relative degree, which has no basis of comparison. For this reason, it is considered broad and relatively unlimited. The examiner asserts that the claimed physical property of the tube (in this case, a substantially unchanged second circumference upon expansion 100%) is present in the prior art material to some extent even though not explicitly recited. Therefore, the examiner hereby burdens the applicant to show that these properties are not present in the prior art. Since the material of the tube is the same as what is being claimed, the blood liner inherently possesses the same unchanged second circumference in response to internal pressure as the Applicant's claimed blood liner tube. Regarding claims 3,4,15,16 Myers et al. also disclose the liner comprises a wall with a thickness less than 0.25mm and can be about 0.1mm thick, col. 15, lines 50,51. With respect to claim 5, PTFE inherently possesses nodes interconnected by fibrils. Regarding claims 6,7, Myers disclose that films can be applied a helical layers about the tube, col. 4, lines 55-58. Regarding claim 9, Myers also discloses the film is thermally bonded to the tube, col. 19, lines 1-14. With respect to claim 29, the liner can be a living blood vessel, col. 3, lines 59-62. Regarding claim 30, Myers discloses an anastomosis can be a site of repair, col. 14, lines 11-37.

Claims 1,5,9,10,14,17,19,20,22-26,28-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Tu et al. (5061276). Tu et al. disclose (col. 12, lines 20,21) a tube with an outer covering, Fig. 2. Tu also discloses the device can be used as a graft, col. 4, lines 53-55. Tu additionally discloses the tube is porous, col. 3, lines 4-6. Tu discloses the graft tube is made of polytetrafluoroethylene and has a covering of "essentially" polytetrafluoroethylene, col. 3, lines 45,46, abstract. Please note that the Examiner is interpreting "essentially" as a comprising clause that does not exclude other materials. However, it is understood that a large amount can be understood to be encompassed by this. Tu does disclose that when a blend of PTFE is used that the majority is 95% PTFE (col. 14, lines 15-20) and can thus be considered "essentially" PTFE. Tu et al. disclose the graft can be sutured to a conduit, col. 5, lines 55-63. Tu also discloses the graft circumference increases as a result of the blood pressure, col. 5, lines 46-48. Tu additionally discloses the tube can be expanded such that the second circumference (10mm) is at least 100% larger than the tube's original circumference (4mm) prior to the application of internal pressure, col. 10, lines 34-38. The polytetrafluoroethylene tube is disclosed as having a microstructure of nodes interconnected by fibrils, col. 7, lines 19-22. The circumference is fully capable of being increased by inflating a balloon. Tu also discloses the tube is placed on a tapered mandrel such that it forms a tapered end with a larger circumference at one end and a smaller second circumference at an opposing end, col. 10, lines 33-35. Because the same materials as claimed are disclosed by the prior art, the examiner asserts that the claimed physical properties are present in the prior art material to some extent even

though they are not explicitly recited. Therefore, the examiner hereby burdens the applicant to show that these properties are not present in the prior art. Regarding claim 27, it can be construed that an interior liner is present on the graft when multiple layers of PTFE are used, col. 3, lines 35-38.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 6,7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tu et al. '276 in view of Eilentropp (4791966). Tu et al. is explained supra. Tu also discloses (col. 11, lines 7-11,col. 12, lines 1-4) that layers of film applied to the tube are helical. However, Tu et al. do not explicitly disclose the PTFE layers are helical. Eilentropp teaches (Fig. 5) that PTFE film (abstract) can be applied helically about a tube. Eilentropp also teaches that helically wrapping prevents leakage, col. 7, line 68, col. 8, lines 1-3. Therefore, it would have been obvious to one of ordinary skill in the art to apply the PTFE layers helically as taught by Eilentropp about the tube of Tu et al. such that it improves its compatibility and resistance to leakage.

Claims 18,32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tu et al. '276 in view of Hughes et al. (4728328). Tu et al. is explained supra. However, Tu does not disclose a tube that is branched with three ends. Hughes et al. teach a tubular prosthesis that is branched with three ends, Fig. 12. It would have been obvious to one of ordinary skill in the art to use the branched tubular form as taught by Hughes with the

prosthesis of Tu et al. in a vessel such as the trachea requiring replacement to the two bronchi.

Claims 3,4,15,16,21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tu et al. '276 in view of Lee (5123917). Tu et al. is explained as before. However, Tu fails to disclose the wall thickness to be less than 0.1mm or use of a stent used to secure the graft to a conduit. Lee teaches that the thickness of the graft equal to about 0.1mm, col. 5, lines 56-59. Lee additionally teaches (col. 5, lines 25-31) a stent is used to secure a graft to a blood conduit, Figs. 1,4. Lee also teaches the stent is used to provide some stiffness to the graft to support the vessel, col. 3, lines 5-9,20-24. It would have been obvious to one of ordinary skill in the art to utilize a stent or stents as taught by Lee in the graft of Tu et al. such that it provides greater support to the vessel it is implanted in. Additionally, the use of a thickness of about 0.1mm for the wall of the graft as taught by Lee in the implant of Tu et al. provides a flexible and small profile for easier delivery to the implantation site.

Response to Arguments

Applicant's arguments filed 6/11/09 have been fully considered but they are not persuasive. Applicants argue that Tu teaches an embodiment with a PTFE mixed with an elastomer. First the Examiner would like to emphasize it can be interpreted in the numerous recitations of Tu, that it is clear that it mentions PTFE alone as a covering which clearly meets the limitations of the claim. Additionally, the language of "essentially" PTFE, it can also be said that while Tu does disclose blends of PTFE with

elastomers, the majority of the blend is PTFE and thus can be said to be "essentially" PTFE.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (7am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738